UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

TPP TRIAL DEFENDANTS' OMNIBUS MOTION FOR SUMMARY JUDGMENT[1]

[1] This Motion for Summary Judgment concerns the claims designated in the Court's Case Management Order No. 32 (the "TPP Trial Claims"); specifically, the claims of Plaintiff MSP Recovery Claims, Series LLC, as class representative of TPP Breach of Express Warranty subclass b, TPP Breach of Implied Warranty subclass d, TPP Fraud subclass c, and TPP State Consumer Protection Laws subclass a (collectively, the "TPP Classes"), against the TPP Trial Defendants. (ECF 2343 at 1-2.) Accordingly, this motion is limited to the TPP Trial Claims, and is presented without waiver of any arguments for summary judgment with respect to any other claims asserted by any Plaintiff as to any Defendant(s) in this multi-district litigation.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

RULES

OTHER AUTHORITY

INTRODUCTION

MSP Recovery Claims, Series, LLC ("MSP") seeks to recover on behalf of numerous third-party payors ("TPPs" or "Plaintiffs") under the express warranty laws of 20 states, the implied warranty laws of seven states, the common-law fraud standards of 23 states and the consumer-protection statutes of 18 states. The gravamen of their claim is that they should be reimbursed for covering life-saving "valsartan-containing drugs" or "VCDs" that were supposedly rendered worthless by the alleged presence of N-Nitrosodimethylamine ("NDMA") or N-Nitrosodiethylamine ("NDEA"). The TPP Trial Defendants[2] are entitled to summary judgment on all of Plaintiffs' claims.

First, Plaintiffs cannot prove many elements of their claims. The claims for breach of implied and express warranty fail for lack of pre-suit notice and are at least partially time-barred. Plaintiffs' implied warranty claims separately fail because Plaintiffs lack privity with Defendants and cannot establish that the VCDs were unmerchantable. Plaintiffs' claims for breach of express warranty fail because Plaintiffs have no evidence that Defendants made (much less breached) any express

[2] The "TPP Trial Defendants" or "Defendants" are: (i) Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Prinston Pharmaceutical Inc., and Solco Healthcare U.S., LLC (collectively, "ZHP"); (ii) Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, and Actavis Pharma, Inc. (collectively, "Teva"); and (iii) Torrent Pharmaceuticals Ltd. and Torrent Pharma, Inc. (collectively, "Torrent").

warranty. Plaintiffs' fraud-based and consumer protection claims fail because they have no evidence that Defendants engaged in any false or misleading statements or concealment or that Plaintiffs relied on Defendants' statements or omissions. And the consumer-protection claims are not actionable under some states' laws because Plaintiffs are not consumers and/or the claims cannot be asserted on a class basis.

Second, all of Plaintiffs' claims fail under the applicable state laws for lack of injury. Plaintiffs' theory that the VCDs were "worthless" fails as a matter of law because the factual record is undisputed that the VCDs delivered their full therapeutic benefit, as affirmed by the recent testimony of Plaintiffs' damages expert, Dr. Rena Conti. Although the Court permitted Plaintiffs' theory of injury to proceed past the pleading and class-certification stages, the newly effective amendment to rule 702 and Dr. Conti's more recent admissions weigh in favor of excluding this factually and legally unsupportable theory, leaving Plaintiffs with no evidence capable of demonstrating that they sustained any injury in this case.

Third, all of Plaintiffs' claims fail because they cannot prove that any misrepresentations, omissions or warranties made by any Defendant actually caused them any harm. Plaintiffs cannot carry their causation burden for even a single class member, much less on a classwide basis.

Fourth, Plaintiffs' damages claims fail because Dr. Conti's proposed classwide model for calculating damages is untethered to the subclasses certified by

the Court. Dr. Conti purports to calculate damages based on the "point of sale" where each prescription was filled, ***not*** where each TPP "paid any amount of money" for the VCDs, as the class definitions require. There is no dispute that TPPs pay for VCDs through an intermediary like a pharmacy benefits manager ("PBM"), not at the point of sale. As a result, Dr. Conti's model necessarily includes recoveries for TPPs that paid for VCDs outside of the subclass states and whose claims are governed by other states' laws. And whatever laws govern, Plaintiffs' theory of damages fails because they received the benefit of their bargains and did not have out-of-pocket losses, and they cannot prove entitlement to punitive damages. Indeed, some of the relevant states do not even allow such damages.

For all of these reasons, the TPP Trial Defendants are entitled to summary judgment.

FACTUAL BACKGROUND

The facts relevant to this motion are set forth in detail in the TPP Trial Defendants' Omnibus Statement of Material Facts Not in Dispute ("SUMF"), which is incorporated herein, and are summarized briefly below.

Beginning in July 2018, the ZHP, Teva and Torrent Defendants voluntarily recalled various finished-dose VCDs after trace amounts of NDMA were identified in the VCDs. (SUMF ¶¶ 2-5, 77.) In its first announcement regarding the valsartan recall, the FDA stated that "the presence of NDMA was unexpected and [was]

thought to be related to changes in the way the active substance was manufactured." (*Id.* ¶ 61 (alteration in original).) A statement issued by FDA Commissioner Scott Gottlieb clarified that "[b]efore [the agency] undertook [an] analysis [following the discovery of NDMA in ZHP's valsartan API], neither regulators nor industry fully understood how NDMA could form during this process." (*Id.* ¶ 62 (third alteration in original).) Accordingly, at the time of the recalls, there were no validated, required, or industry-standard methods or practices to test for the presence or absence of NDMA or NDEA in VCDs. (*Id.* ¶ 69.) In fact, the FDA did not develop or issue any methods for the detection of NDMA or NDEA in VCDs until October 11, 2018, months after the valsartan recalls. (*Id.* ¶ 74.)

Dr. Gottlieb also explained that "NDMA's properties make it difficult to find," and "[b]ecause it was not anticipated that NDMA would occur at these levels in the manufacturing of the valsartan API, manufacturers would not have been testing for it." (*Id*. ¶ 63 (alteration in original).) Plaintiffs' organic chemistry expert, Dr. Stephen Hecht, admits that nobody would have "identified NDMA . . . unless they were specifically looking for it, because the peaks would be too small." (*Id*. ¶ 71.)

There is no evidence that any of the VCDs were recalled from the market because of efficacy concerns; nor is there evidence that any of the VCDs failed to provide effective blood pressure treatment to the patients who purchased and used

them. (*See, e.g.*, *id.* ¶ 79 (Plaintiffs' expert, Dr. Conti, admitting that she could not identify any scientific evidence that generic valsartan available on the market between 2012 and 2018 was ineffective in treating the condition); *id.* ¶ 80 (Plaintiffs' expert, Dr. Najafi, testifying that he cannot dispute that the medications "lower[ed] blood pressure in adults and children") (alteration in original).)

Further, the evidence in the record establishes that any risk posed by the presence of a trace impurity in the medication was extremely low. Indeed, the FDA stated in its initial news release about the recall that patients "should continue taking their medicine until they have a replacement product." (*Id.* ¶ 81.) The FDA took this position based on a finding that "[t]he risk associated with abruptly discontinuing the use of these important medicines far outweighs the low risk that our scientists estimate to be associated with continuing the medicine." (*Id.* ¶ 82 (alteration in original).) Specifically, the FDA estimated that, "if 8,000 people took the highest valsartan dose (320 mg) from NDMA-affected medicines daily for four years (the amount of time we believed the affected products had been on the U.S. market), there may be ***one*** additional case of cancer over the lifetimes of these 8,000 people beyond the average cancer rate among Americans," and that "[m]ost patients who were exposed to the impurity through the use of valsartan received less exposure than this worst-case scenario." (*Id.* ¶ 78 (emphasis added).) With respect to NDEA—which was detected in some VCDs later in 2018—the FDA estimated an even lower

risk: one possible additional case of cancer over the lifetimes of 18,000 people. (*See id.*)

Despite the undisputed efficacy of the VCDs in treating hypertension and the FDA's acknowledgement that the trace impurities posed a low risk (if any) of cancer (*id*. ¶¶ 77-78), MSP alleges that the product was "worthless" due to the presence of the trace impurities. (ECF 1708 (Third Am. Consol. Econ. Loss Cl. Action Compl.) ¶ 4.) Accordingly, MSP contends that it is entitled to recover all of the money that its two TPP assignors (Emblem and SummaCare) allegedly spent on their insureds' prescriptions for the recalled VCDs. (SUMF ¶ 2.)

Plaintiffs also allege that Defendants breached warranties, engaged in fraud and violated consumer protection statutes by selling the VCDs at issue. (*Id.* at n.2.) But there is no evidence that the TPP Trial Defendants made any warranties or representations on labels, websites, or anywhere else regarding the presence or absence of NDMA or NDEA in their respective valsartan API or VCDs. (*Id.* ¶ 83.) Nor is there any evidence that Emblem, SummaCare, or any TPP class member received or relied upon any representations from any TPP Trial Defendant. (*Id.* ¶ 84.) To the contrary, SummaCare's representative testified that SummaCare "does not have any direct relationship with manufacturers," and "we do not have any warranties in place with manufacturers directly," and Emblem's representative acknowledged that she was unaware of any communications with, or review of, any

representations, website, or literature regarding VCDs from any Defendant. (*Id*. ¶¶ 84-85.)

ARGUMENT

The Court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Once a defendant has shown that the plaintiff has "failed to establish one or more essential elements of its case," the plaintiff "'must point to concrete evidence in the record'; mere allegations, conclusions, conjecture, and speculation will not defeat summary judgment." *Affinity Healthcare Grp. Voorhees, LLC v. Twp. of Voorhees*, 624 F. Supp. 3d 494, 509-10 (D.N.J. 2022) (citation omitted). Because this Court sits in diversity, it is required to faithfully apply "the current law of the appropriate jurisdiction, and leave it undisturbed." *City of Philadelphia v. Lead Indus. Ass'n*, 994 F.2d 112, 123 (3d Cir. 1993).

According to this Court's prior ruling, Plaintiffs' claims are governed by "the law[s] of [their] home state[s]"—i.e., where each TPP is located. (ECF 818 at 10.) Yet, each of the TPP subclass definitions is limited to specific states in which TPP subclass members "paid any amount of money" for VCDs, which may or may not be their home states. (ECF 2532-6.)[3] This disconnect between the state whose law

[3] For example, TPP breach of implied warranty subclass d includes all TPPs that "paid any amount of money in Alabama, New York, Ohio, Oregon, Tennessee, Utah, or Vermont" for an at-issue VCD. (ECF 2532-6 at 4-5.)

governs (i.e., the TPP's home state) and the states encompassed by the subclass definitions (i.e., the state where each TPP paid for valsartan) makes it impossible to discern what law governs each unnamed subclass member's claims. With respect to named plaintiff MSP, for example, its claims are governed by the laws of New York and Ohio because the two TPPs that assigned their claims to MSP are at home in those states. But it is not clear where the underlying claims were paid because Plaintiffs have made no attempt to identify where each TPP (including even MSP's assignors) paid for at-issue VCDs. Moreover, the identities and home states of other subclass members are unknown, making it impossible to determine what laws govern their claims. The mismatch between the defined subclasses and the Court's prior choice-of-law ruling makes it impossible and impractical for the TPP Trial to proceed. For present purposes, however, this motion assumes without conceding (and contrary to the law of the case) that the claims at issue are governed by the 43 jurisdictions identified across the four subclasses. Plaintiffs' claims fail under those laws for multiple reasons.

I. PLAINTIFFS CANNOT SATISFY SEVERAL ELEMENTS OF THEIR CAUSES OF ACTION.

A. Plaintiffs' Breach Of Warranty Claims Fail For Multiple Reasons.

1. Plaintiffs' Breach Of Warranty Claims Fail For Lack Of Notice And Are At Least Partially Stale.

Defendants are entitled to summary judgment on all of Plaintiffs' claims for

breach of express or implied warranty for two reasons.

First, it is undisputed that MSP, its assignors, and the TPP class members did not give notice to any Defendant of any purported breach of warranty prior to commencing suit—a fundamental element of every state warranty law in question, as this Court has recognized. (*See* ECF 2261 at 44; ECF 2261-1 at F-9, F-26 to F-27, F-32 to F-50; ECF 2261-2 at G-45, G-48 to G-53.)[4] Emblem expressly testified that it was not aware that it or any other TPP provided pre-suit notice. (SUMF ¶ 112.) Nor is there any other evidence of pre-suit notice in the record; indeed, this element cannot be practically proven in a class action. *See Cohen v. Implant Innovations, Inc.*, 259 F.R.D. 617, 624-25 (S.D. Fla. 2008).

In its motion-to-dismiss ruling, the Court held that Plaintiffs had adequately pled notice by relying on pre-suit notice letters, even though those letters were sent on behalf of consumer plaintiffs, not MSP, its assignors, or any other TPPs. (*See*

[4] *See also, e.g.*, *Hobbs v. Gen. Motors Corp.*, 134 F. Supp. 2d 1277, 1285 (M.D. Ala. 2001) (holding that Alabama law requires pre-suit notice and the filing of a complaint does not satisfy the notice requirement or raise a sufficient question of fact for the jury); *Williams v. Mozark Fire Extinguisher Co.*, 888 S.W.2d 303, 305-06 (Ark. 1994) (holding that notice is a "condition precedent" to recovery and "the notice must be more than a complaint"); *Fire Supply & Serv., Inc. v. Chico Hot Springs*, 639 P.2d 1160, 1164 (Mont. 1982) ("To recover damages for a breach of warranty, the buyer must plead and prove that he gave the seller notice of the breach within a reasonable time after it was discovered or be barred from any remedy."); *In re Ford Motor Co. E-350 Van Prods. Liab. Litig.*, MDL No. 1687, 2010 U.S. Dist. LEXIS 68241, at *162 (D.N.J. July 9, 2010) (noting that under Texas law, the filing of a complaint does not give sufficient notice, as notice must be given pre-suit).

ECF 775 at 11-12; ECF 577-2 at 2, 15, 17, 20, 23, 26, 29.) Because the notice requirement is plaintiff-specific, however, the fact that a handful of ***consumers*** may have notified certain Defendants cannot suffice to withstand summary judgment against the ***TPPs***. *See Drobnak v. Andersen Corp.*, 561 F.3d 778, 784 (8th Cir. 2009) (fact that other named plaintiffs provided notice was insufficient to satisfy notice requirement as to the two plaintiffs who did not); *Fowler v. White*, 85 So. 3d 287, 291-92 (Miss. 2012) (trial court properly held that the affidavit submitted by plaintiff did not satisfy pre-suit notice requirement "because it did not specify that [counsel] had mailed presuit notice in Fowler's case as opposed to counsel's other cases against the defendants"); *Colpitts v. Blue Diamond Growers*, 527 F. Supp. 3d 562, 590 (S.D.N.Y. 2021) ("Plaintiff's failure to satisfy the pre-suit notice requirement is fatal to his breach of express warranty claim.").

The Court also appeared to reason at the pleading stage that any "formal pre-suit pleading requirements" may be obviated by the issuance of voluntary recalls by manufacturers of the VCDs, who necessarily "recognized that lawsuits for injury . . . would likely ensue." (ECF 775 at 12.) But it is well-established that "[r]ecall notices do not satisfy the notice requirement," *In re Ford Motor Co. Speed Control Deactivation Switch Prods. Liab. Litig.*, MDL No. 1718, 2007 WL 2421480, at *6 (E.D. Mich. Aug. 24, 2007), because the purpose of notice "is to allow the seller an opportunity to resolve the dispute regarding an alleged breach before the buyer

initiates a lawsuit," *Am. Fed'n of State Cnty. & Mun. Emps. v. Ortho-McNeil-Janssen Pharms., Inc.*, No. 08-cv-5904, 2010 WL 891150, at *6-7 (E.D. Pa. Mar. 11, 2010) (dismissing implied warranty claim for lack of pre-suit notice where plaintiffs argued constructive notice due to recall).[5]

Second, substantial portions of Plaintiffs' claims are barred because they are untimely. The statutes of limitations in the implied warranty subclass d states are all four years. (*See* ECF 2261-2 at G-45, G-48 to G-53.) The relevant periods for the states in express warranty subclass b are either six years (Mississippi, South Carolina, and Wisconsin), five years (Florida) or four years (all other states). (*See* ECF 2261-1 at F-9, F-26 to F-27, F-32 to F-50.) Importantly, with the exception of Florida's express warranty law, none of the other relevant state warranty laws recognizes a discovery rule; rather, breach of warranty claims accrue at tender of delivery. (*See id.*) Although Plaintiffs are seeking to recover for VCDs manufactured between 2012 and 2019, a significant portion of that period is outside the relevant

[5] At class certification, the Court relied on *Chemtrol Adhesives, Inc. v. American Manufacturers Mutual Insurance Co*., 537 N.E.2d 624 (Ohio 1989), for the proposition that Ohio's pre-suit notice requirement was "iffy." (ECF 2261-2 at G-49.) However, "[s]ince *Chemtrol*, Ohio courts and federal courts applying Ohio law have continued to hold that a plaintiff must notify a defendant of the alleged breach prior to the complaint." *Lincoln Elec. Co. v. Technitrol, Inc.*, 718 F. Supp. 2d 876, 883 (N.D. Ohio 2010) (collecting cases). In any event, *Chemtrol*'s holding that the reasonableness and timeliness of notice are ordinarily fact questions has no bearing on Plaintiffs' claims because they have failed to present any evidence of notice.

statutes of limitations. For example, warranty claims arising out of the purchase of VCDs in 2012, 2013 and some purchases in 2014 would be time-barred under most of the state warranty laws in question because they necessarily accrued more than four years prior to commencement of MSP's TPP lawsuit in 2018. And because those states do not recognize any discovery rule for warranty-based claims, it is of no moment whether the TPPs were aware of the presence of NDMA or NDEA when they paid for the VCDs. Accordingly, the Court should grant Defendants summary judgment on the breach of warranty claims that arose out of purchases of the VCDs outside the applicable statutes of limitations.

2. Plaintiffs' Implied Warranty Claims Also Fail For Lack Of Privity And Unmerchantability.

Defendants are separately entitled to summary judgment on Plaintiffs' implied warranty claims because they cannot establish privity or unmerchantability.

First, the class members cannot prove that they are in privity of contract with Defendants, as required under Alabama, New York, Ohio, Oregon, Tennessee, Utah and Vermont law. (*See* ECF 2261 at 44; ECF 2261-2 at G-45, G-48 to G-53.)[6]

[6] *See also, e.g.*, *Blackmon v. Powell*, 132 So. 3d 1, 6 (Ala. 2013) ("The linchpin of a breach-of-the-implied-warranty-of-merchantability claim is privity[.]"); *Jackson v. Eddy's LI RV Ctr., Inc.*, 845 F. Supp. 2d 523, 530 (E.D.N.Y. 2012) (implied warranty claims can only be brought "by those in privity with the named defendant"); *Curl v. Volkswagen of Am., Inc*., 871 N.E.2d 1141, 1147 (Ohio 2007) (similar); *Davis v. Homasote Co.*, 574 P.2d 1116, 1117 (Or. 1978) (en banc) ("[Oregon] has adhered to the rule that privity of contract is essential before a purchaser can recover economic loss from a manufacturer for breach of implied

Plaintiffs had no direct contractual relationship with the TPP Trial Defendants and generally do not even contract directly with pharmacies to pay for prescriptions. Rather, TPPs contract with one or more intermediaries such as PBMs. (SUMF ¶ 107.)

The Court declined to dismiss the implied warranty claims under, *inter alia*, Alabama, Ohio, and Vermont law, on the ground that TPP Plaintiffs adequately pled that they were third-party beneficiaries of express warranties to the ultimate consumer. (*See* ECF 775 at 21.) But, to the extent states have recognized a third-party beneficiary exception to the privity requirement in the implied warranty context, they have, at most, permitted a "plaintiff-***consumer*** to recover from a defendant-manufacturer as the intended ***end user*** of the product." *Traxler v. PPG Indus., Inc.*, 158 F. Supp. 3d 607, 626 (N.D. Ohio 2016) (emphases added). That principle cannot salvage Plaintiffs' implied warranty claims because there is no dispute that consumers (not TPPs) were the end users of VCDs.

The Court's prior ruling that New York does not require privity when the consumed products are food or drugs also does not apply here in light of subsequent

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warranty."); *Memphis-Shelby Cnty. Airport Auth. v. Ill. Valley Paving Co.*, No. 01-3041 B, 2006 WL 3041492, at *2-3 (W.D. Tenn. Oct. 26,2006) (similar); *Davencourt at Pilgrims Landing Homeowners Ass'n v. Davencourt at Pilgrims Landing, LC*, 221 P.3d 234, 252 (Utah 2009) ("Privity of contract is required to bring a claim for breach of the implied warranty."); *Mainline Tractor & Equip. Co. v. Nutrite Corp.*, 937 F. Supp. 1095, 1108 (D. Vt. 1996) ("the Vermont Supreme Court would not abandon the privity requirement" for implied warranty actions).

precedent. (*See* ECF 2261 at 43.) As Judge Arleo more recently explained in dismissing similar implied warranty claims brought by MSP, the food/drug exception was abrogated by New York's adoption of the UCC. *See In re Metformin Mktg. & Sales Prac. Litig.*, No. 20-cv-2324, 2022 WL 970281, at *12 (D.N.J. Mar. 30, 2022); *see also Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283, 296 (S.D.N.Y. 2015) (dismissing claims brought on behalf of a putative New York subclass for breach of implied warranty; older cases "holding that privity is not required with regard to implied warranty claims 'concerning sealed food products or medicines'" "preceded the enactment of the UCC, which displaced [them]") (citations omitted).

Second, Plaintiffs' implied warranty claims also cannot proceed because Plaintiffs cannot prove that the VCDs were unmerchantable. State-law differences on the merchantability requirement "reflect divergent judicial philosophies on the scope and content of the breach of implied warranty standard, which may significantly [a]ffect the wording of jury instructions, the standard for a directed verdict and ultimately, the outcome of the case." *Walsh v. Ford Motor Co.*, 130 F.R.D. 260, 271-73 (D.D.C. 1990). Defendants are nevertheless entitled to summary judgment under any standard because there is no evidence that the VCDs were unfit for their intended purpose of managing high blood pressure. *See Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401, 411-12 (11th Cir. 20111)

(affirming dismissal of TPP's claim for breach of implied warranty under New Jersey law where TPP "has failed to identify any case law to support its theory that the potential of a drug to cause harmful side effects, in the abstract, renders a drug per se unmerchantable, even as to plaintiffs that did not suffer the side effects"). To the contrary, the record shows that the presence of NDMA or NDEA impurities did not diminish the efficacy of the TPP Trial Defendants' VCDs, and that the VCDs provided full therapeutic benefits. (*See* SUMF ¶¶ 79-82.)

At the motion-to-dismiss stage, the Court, relying on *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076 (11th Cir. 2019), reasoned that "contaminated drugs, even if medically efficacious for their purpose," can support a viable claim for breach of implied warranty. (ECF 775 at 20.) *Debernardis*, however, is inapposite for multiple reasons. First, *Debernardis* involved Article III standing, ***not*** whether the drug at issue was merchantable. Second, the Eleventh Circuit expressly "cautioned" courts that its holding was "limited to the specific facts alleged in th[at] case"—namely, that the FDA had warned the manufacturers before they sold the purportedly adulterated supplements that they were illegal to sell. *Debernardis*, 942 F.3d at 1082, 1088. Here, by contrast, the VCDs were legal to sell, and the FDA never instructed the TPP Trial Defendants to stop selling them before requesting a voluntary recall. *See In re Zantac (Rantidine) Prods. Liab. Litig.*, MDL No. 2924, 2023 U.S. Dist. LEXIS 129339, at *312-13 (S.D. Fla. July 25, 2023) (distinguishing

Debernardis). Moreover, the FDA confirmed the health benefits of VCDs after the recall by recommending that consumers continue to use their medicine until they could obtain replacements. (SUMF ¶ 81.) In short, the only record evidence is undisputed that the VCDs ***did*** perform as intended, defeating any claim that they were not merchantable.

3. Plaintiffs Have No Evidence That Any Express Warranty Existed, Was Breached Or Was Relied On.

Defendants are separately entitled to summary judgment on Plaintiffs' express warranty claims because Plaintiffs cannot prove that: (1) Defendants made any express warranty; (2) Defendants breached any express warranty; or (3) the class members relied on such a purported warranty.

At the motion-to-dismiss stage, the Court held that Plaintiffs had sufficiently pled the existence of an express warranty based on the naming of the VCDs as valsartan and purported "marketing" of the VCDs as the "chemical equivalent" of branded valsartan listed in the Orange Book. (ECF 775 at 13-14.) But at this stage, the undisputed record disproves Plaintiffs' allegations. Summacare's representative testified that it had no "warranties in place" with the TPP Trial Defendants, and Emblem's representative was not aware of any express warranties. (SUMF ¶¶ 84-85.) Moreover, the Court previously excluded Plaintiffs' only expert evidence of an express warranty (i.e., Dr. Kaliopi Panagos's opinion that a generic drug listing and rating in the Orange Book supposedly constitutes a manufacturer's "warranty"), as

exceeding her expertise. (ECF 2261 at 94.)

Nor could Plaintiffs prove that Defendants breached any express warranty, even if one existed. The presence of trace levels of NDMA or NDEA in the VCDs did not violate any purported warranty that these VCDs were "the same" or were generic versions of their reference listed drugs ("RLDs") (SUMF ¶ 89) because the levels of all impurities in the VCDs at issue were within the specification limits approved by the FDA, and the VCDs remained pharmaceutically equivalent and bioequivalent to the RLDs. (*Id.* ¶¶ 86-94.)

Finally, Plaintiffs' express warranty claims also fail for lack of reliance. As reflected in the annotated state-law charts adopted by the Court at the class certification stage, reliance is an essential element of the laws of 14 out of the 20 states in the express warranty subclass at issue in this trial. (ECF 2261-1 at F-9, F-26 to F-27, F-32 to F-50.)[7] And as just discussed, Plaintiffs' corporate representatives were not even aware of the existence of any purported warranties. (*See, e.g.*, SUMF ¶¶ 84-85.) It follows perforce that neither MSP nor its assignors could have possibly relied on an alleged warranty of which they were unaware.

[7] *See also, e.g., Madden v. Mercedes-Benz USA, Inc.*, 481 S.W.3d 455, 463 (Ark. Ct. App. 2016); *Thomas v. Amway Corp.*, 488 A.2d 716, 720 (R.I. 1985); *Thursby v. Reynolds Metals Co.*, 466 So. 2d 245, 250 (Fla. Dist. Ct. App. 1984). The fact that more than half of the relevant states require reliance while others do not underscores the fundamental manageability and fairness problems that would plague any class trial.

Although Dr. Panagos previously sought to fabricate warranties and reliance out of Orange Book listings, this Court properly excluded Dr. Panagos' warranty and reliance opinions as "outside the purview of her expertise." (ECF 2261 at 94.) Indeed, no court has ever held that Orange Book listings constitute a warranty in this context. And for good reason. It is undisputed that P&T Committees—which evaluate medications for inclusion on formularies—do not consider individual manufacturers' generic medications in their decision-making; nor do they rely on the Orange Book. (*See* SUMF ¶¶ 114, 119-20.) Instead, they factor in various other non-manufacturer-provided information, such as literature, relevant patient utilization, economic data and relevant patient experiences. (*Id.* ¶ 122.)

For these reasons, too, the Court should grant summary judgment to Defendants on Plaintiffs' express warranty claims.

B. The Class Members' Fraud-Based Claims Fail For Multiple Reasons.

Defendants are also entitled to summary judgment on Plaintiffs' common-law fraud and consumer-fraud claims for several independent reasons.

1. MSP Cannot Establish Any False Or Deceptive Statement Or Omission.

As a threshold matter, MSP cannot establish that Defendants' alleged conduct was fraudulent or deceptive, and the undisputed record proves it was not. Although there are material "variations among state consumer protection laws" and common-

law fraud regimes with regard to the type of conduct that is actionable, *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, No. 17-md-2785-DDC-TJJ, 2020 WL 1180550, at *57 (D. Kan. Feb. 27, 2020), these varying standards require, at a minimum, evidence of a false or deceptive statement or omission, *see In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 113 F.3d 1484, 1498 (8th Cir. 1997) ("Without evidence of a false representation, the misrepresentation claim cannot succeed . . . ."); *E. R. Squibb & Sons, Inc. v. Stickney*, 274 So. 2d 898, 907 (Fla. Dist. Ct. App. 1973) (requiring evidence "which can reasonably support a finding" that defendant "willfully ignored, concealed, or suppressed" information to support fraudulent omission claim); *Parker v. United Indus. Corp.*, No. 17 Civ. 5353 (GBD), 2020 WL 5817012, at *3 (S.D.N.Y. Sept. 29, 2020) (granting summary judgment on consumer fraud claim where plaintiff did not adduce evidence that "the representations on the [product] label [we]re false statements").

As this Court previously recognized, regardless of whether Plaintiffs' claims are couched as misrepresentations or omissions, the crux of Plaintiffs' theory of fraud is an alleged falsehood "that the VCDs were therapeutically equivalent to the reference listed drug, complied with [current good manufacturing practices ("cGMPs")], were unadulterated, and properly branded." (ECF 818 at 14; *see also, e.g.*, *id.* (omission-based theory is the "inverse of the first").) But this Court has

already excluded the opinion of Plaintiffs' expert Dr. Najafi that valsartan API is not bioequivalent to branded valsartan. (*See* ECF 2261 at 91.)[8] And even if such an opinion were admissible, Dr. Najafi admitted in deposition testimony that the presence of impurities does not implicate pharmaceutical equivalence or bioequivalence. (*See* SUMF ¶ 92.) Nor does the presence of an impurity not listed in the Abbreviated New Drug Application ("ANDA") nullify the ANDA approval. *See United States v. Vepuri*, 74 F.4th 141, 150 (3d Cir. 2023) (an FDA-approved drug still has "the same composition and labeling . . . for which an approval of an ANDA is effective" despite the presence of impurities) (footnote omitted). Because there is no evidence that the presence of nitrosamines affected the therapeutic equivalence of the VCDs, Plaintiffs' theory that Defendants engaged in fraudulent conduct fails.

2. Plaintiffs Cannot Satisfy The Reliance Requirement Of Their Fraud-Based Claims.

Plaintiffs also cannot prove the reliance elements of their common-law fraud claims, as required for every state in fraud subclass c (ECF 2261 at 45; ECF 2261-3

[8] While Dr. Najafi seeks to testify that ZHP violated cGMPs, his ancillary exposure to regulatory issues while working as a chemist does not qualify him to opine on FDA matters, as elaborated in Defendants' pending *Daubert* motion. *See Rheinfrank v. Abbott Lab'ys, Inc.*, 680 F. App'x 369, 376, 381 (6th Cir. 2017) (affirming ruling precluding expert with no FDA experience from opining on compliance with FDA requirements).

at H-3, H-13, H-18 to H-19, H-22, H-29, H-31, H-33, H-40 to H-54),[9] and for eight of the states in consumer fraud subclass a (ECF 2261-4 at I-6 to I-33 (collecting cases reflecting that Arizona, California, Maryland, North Carolina, Oregon, Pennsylvania, Vermont and West Virginia require reliance)).[10]

The record here lacks any evidence that MSP's assignors, SummaCare and Emblem, or any other TPP subclass member, relied on any purported misrepresentations or omissions. *See In re Testosterone Replacement Therapy Prods. Liab. Litig.*, MDL No. 2545, 2019 U.S. Dist. LEXIS 24063, at *427-28 (N.D. Ill. Feb. 14, 2019) (granting summary judgment on federal RICO and Ohio common law misrepresentation claims asserted by a TPP because "[e]ven if a reasonable jury

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[9] Defendants note that the states included in subclass c differ with respect to whether reliance must be ***justified***. *Compare Butler v. Yusem*, 44 So. 3d 102, 105 (Fla. 2010) ("Justifiable reliance is not a necessary element" of a fraudulent misrepresentation claim), *with Pasternack v. Lab'y Corp. of Am. Holdings*, 27 N.Y.3d 817, 829 (2016) ("[T]his [c]ourt has stated on a number of occasions that a fraud claim requires the plaintiff to have relied upon a misrepresentation by a defendant to his or her detriment."). Regardless of this distinction in state law, [p]laintiffs have failed to proffer sufficient proof of any reliance, justified or not, from an objective or subjective standpoint.

[10] *See also, e.g.*, *Durell v. Sharp Healthcare*, 108 Cal. Rptr. 3d 682, 687-88 (Ct. App. 2010) ("[A]ctual reliance is an element of the claim."); *Goss v. Bank of Am., N.A.*, 917 F. Supp. 2d 445, 450 (D. Md. 2013) ("To state a claim under the [Maryland Consumer Protection Act], 'the consumer must have suffered an identifiable loss, measured by the amount the consumer spent or lost as a result of his or her reliance on the sellers' misrepresentation.'") (citation omitted); *Kuehn v. Stanley*, 91 P.3d 346, 351 (Ariz. Ct. App. 2004) ("[R]eliance is a required element under Arizona's consumer fraud statute . . . .").

could find that defendants made false or misleading statements to MMO about the safety or efficacy of their TRT drugs, it could not find that MMO relied on them to make any formulary or utilization management decision regarding the drugs"). SummaCare could not identify a single instance of having been exposed to any alleged representation by any Defendant, much less to one that led to it bringing a safety or efficacy concern to the attention of its PBM, which made the ultimate decision to "include or exclude [a drug] from [its] formulary." (*See* SUMF ¶ 123 (alterations in original).) Similarly, the Emblem representative did not know whether anyone at Emblem ever viewed Defendants' websites or VCD-related literature or ever communicated with Defendants about the medications, and she did not notice any change to any Emblem formulary even after the valsartan recall. (*See id.* ¶ 124.) And Plaintiffs have no conceivable reliance evidence as to the other class members.

3. Certain Of The Class Members' Consumer-Protection Claims Are Procedurally Defective.

Plaintiffs' consumer-protection claims fail under certain states' laws for other reasons, too.

First, the consumer-protection claims governed by the laws of the District of Columbia, Hawaii, Missouri, Montana and Ohio cannot proceed because "[o]nly a 'consumer' may bring a private action under" those statutes. *See, e.g.*, *Davis v. Vancil*, 356 P.3d 1044 (table), 2015 WL 4067172, at *5 (Haw. Ct. App. 2015) (citation omitted) (private action can only be brought by "a natural person who,

primarily for personal, family, or household purposes, purchases" goods or services); *Adam A. Weschler & Son, Inc. v. Klank*, 561 A.2d 1003, 1005 (D.C. 1989) (similar). There is no dispute that MSP, its assignees, and the TPP class members are not "consumers" under these statutes. Rather, Plaintiffs are bringing claims "on behalf of commercial purchasers" and, thus, did not purchase the VCDs for "personal, family, or household purposes." *See MSP Recovery Claims, Series, LLC v. Sanofi Aventis U.S. LLC*, No. 3:18-cv-2211-BRM-LHG, 2019 WL 1418129, at *18 (D.N.J. Mar. 29, 2019) (citation omitted) (dismissing Missouri Merchandising Practices Act claim because MSP assignees were commercial purchasers). (*See* SUMF ¶ 107.) Defendants are therefore entitled to summary judgment as to the consumer-fraud claims governed by D.C., Hawaii, Missouri, Montana and Ohio law.

Second, the consumer-protection claims governed by Louisiana and Montana law separately fail because those states expressly prohibit plaintiffs from attempting to assert consumer-fraud claims in putative class actions. *See* La. Rev. Stat. § 51:1409(A) ("Any person who suffers any ascertainable loss of money or movable property . . . as a result of the use or employment by another person of an unfair or deceptive method, act, or practice . . . may bring an action individually ***but not in a representative capacity*** to recover actual damages.") (emphasis added); Mont. Code § 30-14-133(1) (similar). These "class action bars incorporated in the Montana" and Louisiana "consumer protection laws are not preempted by Rule 23" because they

"evince a desire by the state legislature to limit not only the form of the action but also the remedies available." *In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 416-17 (D.N.J. 2018) (citation omitted).

II. PLAINTIFFS CANNOT ESTABLISH A COGNIZABLE INJURY.

All of Plaintiffs' claims separately fail because the TPPs received exactly what they paid for—effective blood pressure medication for their members—and therefore were not harmed. *See, e.g.*, *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774 (SRC), 2009 WL 2043604, at *9 (D.N.J. July 10, 2009) (granting motion to dismiss and rejecting theory of TPP injury where defendant "provide[d] their beneficiaries with the most effective treatment available").

Plaintiffs and their experts acknowledge that the medications at issue worked effectively to lower their enrollees' blood pressure and to reduce hypertension-related risks like artery disease, stroke and heart failure. (*See* SUMF ¶ 79-80.) Moreover, the FDA itself concluded that "the risk to individual patients" from the at-issue VCDs remains "very small" and that someone who took the maximum possible valsartan dose every day the potentially contaminated drugs were on the market would have, at most, just a 1-in-8,000 risk of developing cancer. (*See Id.* ¶ 78.) It also concluded that the health benefits from taking valsartan outweighed these minuscule cancer risks, which is why it recommended that patients continue taking

the allegedly contaminated medication "until [their] doctor or pharmacist provides a safe replacement or a different treatment option." (*Id.* ¶ 82.)

Plaintiffs nonetheless continue to assert that the VCDs they paid for were "worthless" based on Dr. Conti's theory that any medication that fails to comply with FDA regulations must categorically have no economic value even if it treated patients' hypertension. But that position, which Dr. Conti has never backed up with any economic literature, "is not . . . defensible" as a matter of law given that the VCDs proved "beneficial to many patients" and any cancer risk was negligible. *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 68-69 (S.D.N.Y. 2009); *see, e.g., Ctr. City Periodontists Periodontists, P.C. v. Dentsply Int'l, Inc.*, 321 F.R.D. 193, 204 (E.D. Pa. 2017) (plaintiffs' expert "incorrectly presumes that the [the device] is 'worthless' and therefore fails to consider, and could not account for, the device's value," as it benefitted many dentists and their patients, regardless of the alleged inherent defect). That is particularly true because, absent the VCDs, the TPPs would have had to pay for alternative forms of blood pressure medication, some of them much more expensive, or pay costs stemming from the complications of untreated hypertension, which would be more extensive still. (*See* SUMF ¶ 130.) *See Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305, 334 (E.D.N.Y. 2014) (granting summary judgment against TPP plaintiff for lack of "proof of actual injury" based on payments for antibiotics that

performed as intended where there was "no evidence to support" the "highly dubious proposition" that TPPs otherwise "would not have had to pay" for antibiotics).

At the pleading stage, the Court characterized Plaintiffs' "worthless[ness]" theory as "somewhat opaque," but nonetheless permitted it to proceed on the ground that its viability was a "merits" question. (ECF 728 at 3, 5, 8, 11-12, 14-15; *see also* ECF 775 at 19-20.) The Court later reasoned that "[a]t the class certification stage, the methodology of [Dr. Conti] need not be perfect or even legally correct"—essentially, that Defendants' challenge implicated the weight (rather than the admissibility) of Dr. Conti's fundamental opinion. (ECF 2261 at 89.)

At this stage of the proceedings, however, the Court must determine whether it is legally viable to treat effective medication as categorically worthless based on an expert's *ipse dixit*. It is not. *See Am. Fed'n of State Cnty. & Mun. Emps., Dist. Council 47 Health & Welfare Fund v. Ortho-McNeil-Janssen Pharms., Inc.*, 857 F. Supp. 2d 510, 515 (E.D. Pa. 2012) (rejecting "worthless" theory of injury; "[b]ecause there [was] no evidence that any [recalled] patches for which [TPPs] paid were not used as intended, [p]laintiffs ha[d] not shown that they suffered a loss or injury"); *see also Myers-Armstrong v. Actavis Totowa, LLC*, No. C 08-04741 WHA, 2009 WL 1082026, at *4 (N.D. Cal. Apr. 22, 2009) ("That the CDP was adulterated due to a lack of compliance with GMP requirements is not enough, without more, to state a claim.").

Recent changes to the law governing Rule 702 and Dr. Conti's own testimony reinforce this point. An amendment to Rule 702—which took effect earlier this month—now makes clear that the proponent of expert evidence must "demonstrate[]" by a preponderance of the evidence that the expert's opinion is the product of a reliable methodology. *See* Fed. R. Evid. 702. "The amendment also stresses the importance that an expert's opinion must 'stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology' under Rule 702(d)." *Treminio v. Crowley Mar. Corp.*, No. 3:22-cv-00174-CRK, 2023 U.S. Dist. LEXIS 206554, at *9-10 (M.D. Fla. Nov. 17, 2023) (citing Am. Fed. R. Evid. 702 advisory committee's note to 2023 amendment). In short, the amendment to Rule 702 clarifies that it is an "abdication of [the Court's] gatekeeping role" to sidestep close review of an expert's opinions based on tenuous assertions that these are "questions of weight and not admissibility." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 284 (4th Cir. 2021) (quoting advisory committee's note to draft amendment to Rule 702); *see also* Report of the Advisory Committee on Evidence Rules, at 6 (May 15, 2022) ("The Committee concluded that in a fair number of cases, the courts . . . essentially treat[] these questions as ones of weight rather than admissibility, which is contrary to the Supreme Court's holdings that under Rule 104(a), admissibility requirements are to be determined by court under the preponderance standard.").

Dr. Conti has also provided more recent testimony that underscores the factually unsubstantiated nature of her sweeping theory. Dr. Conti recently admitted that any product that "has a market price . . . must have some . . . economic value," undercutting the very premise of her "worthlessness" theory. (SUMF ¶ 128.) Dr. Conti further acknowledged that the "clinical benefit of a product affect[s] its economic value" and "by definition" is "reflected in the demand curve" of the product. (*Id.* ¶ 129 (alteration in original).) Accordingly, Dr. Conti's own recent testimony belies her claim that the VCDs were worthless. For all of these reasons, Plaintiffs' theory of worthlessness is incapable as a matter of law of satisfying their burden as to injury, further requiring summary judgment for Defendants.

III. PLAINTIFFS CANNOT PROVE THAT DEFENDANTS' ALLEGED CONDUCT PROXIMATELY CAUSED ANY INJURY.

Defendants are separately entitled to summary judgment because Plaintiffs cannot prove that any misrepresentations, omissions or warranties made by any Defendant proximately caused their purported losses.

Causation standards vary across the many different states and causes of action that have been bundled together for this trial. *See, e.g.*, *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 183 (3d Cir. 2014) (noting state's "varying" standards of "causation"). Nonetheless, to the extent common principles can be gleaned, the various states and causes of action generally require but-for causation and proximate causation. *See, e.g.*, *Becker v. Cont'l Motors, Inc.*, 709 F. App'x 263,

267 (5th Cir. 2017) (per curiam); *Stearns v. Select Comfort Retail Corp.*, No. 08-2746 JF, 2009 WL 1635931, at *4 (N.D. Cal. June 5, 2009); *Merrill Lynch & Co. v. Allegheny Energy, Inc.*, No. 02 Civ. 7689(HB), 2005 WL 832050, at *4 (S.D.N.Y. Apr. 12, 2005); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action Litig.*, 2009 WL 2043604, at *33. Proximate causation generally imposes a remoteness-based limitation on recovery. *See Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 268-69 (1992) (proximate cause requires "some direct relation between the injury asserted and the injurious conduct alleged").

As courts analyzing issues of remoteness have recognized in cases brought by TPPs, it would be "simply impossible, or close to it, to determine" what (if any) portion of prescriptions were supposedly caused by a drug manufacturer's allegedly deceptive conduct, because "[e]ach decision by each doctor and each patient" is different, and thus "[t]he effect that any alleged misrepresentations had on each decision is unique." *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2010 U.S. Dist. LEXIS 142767, at *23-24 (E.D. La. Mar. 31, 2010) (granting partial summary judgment to pharmaceutical manufacturer in case alleging that purportedly deceptive marketing increased prescriptions); *see also, e.g., UFCW Loc. 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134-35 (2d Cir. 2010) (affirming summary judgment because "[p]laintiffs' theory of liability rests on the independent actions of third and even fourth parties as physicians, PBMs, and PBM Pharmacy and Therapeutics

Committees all play a role in the chain between Lilly and TPPs") (citation omitted); *Sergeants Benevolent Ass'n*, 20 F. Supp. 3d at 315 (similar); *In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp. 2d 397, 433-34 (E.D.N.Y. 2009) (granting summary judgment where Medicaid agency's "individual claim [was] structured on the foundation of many thousands of conceptually separate" prescriptions "due to the need to prove [causation] on an individualized basis" for each prescription).

Sergeants Benevolent Association is instructive. In that case, multiple TPPs brought a nationwide class action against drug companies alleging that they "misrepresent[ed] the safety and efficacy" of an antibiotic and sought to recover for prescriptions paid for by the TPPs. 20 F. Supp. 3d at 308. The defendants moved for summary judgment, arguing that the plaintiffs' theory that "every prescription for [certain indications] caused the [plaintiffs] injury in an amount equal to the amounts they paid" failed as a matter of law. *Id.* at 315 (citation omitted). They further explained that any theory of causation would have to evaluate "what antibiotic would have been prescribed in lieu" of the challenged drug on a prescription-by-prescription basis. *Id.* The court agreed. The court first reasoned that the "length of the causal chain" (which included the FDA, pharmacy benefit managers, doctors and finally the TPP) likely rendered causation "too attenuated." *Id.* at 327. It next found that, even assuming the defendant's alleged failure to disclose safety risks related to the medication led to increased prescriptions (and, by extension, payments by the

TPP), the TPPs' theory of causation could not be proven "through generalized proof" and was "interrupted by the independent actions of prescribing physicians." *Id.* (citation omitted).

These concerns apply with even greater force here. To determine whether Defendants caused Plaintiffs any injury would require a jury to examine each individual prescription to determine whether and to what extent the at-issue VCDs provided value to the patient, in light of his or her individual medical history, including the nature and severity of hypertension and any individualized cancer risks. The jury would next need to evaluate what medication (if any) a plaintiff would have paid for if the at-issue VCDs were not available, and whether that medication would have been cheaper or more expensive than the VCDs in light of the TPP's formulary and benefit structure. Evaluating the claims of even a single TPP (e.g., MSP's assignors) would require thousands or tens of thousands of such inquires. Undertaking that complicated exercise on behalf of the whole class would require millions of individualized inquiries. Plaintiffs have failed to present any evidence for the jury to undertake this task, even if it were possible to do so. Defendants are thus separately entitled to summary judgment for lack of causation.

IV. PLAINTIFFS DO NOT HAVE EVIDENCE TO SUPPORT A COGNIZABLE DAMAGES THEORY.

At a minimum, Defendants are entitled to summary judgment on damages for three reasons. First, Dr. Conti's proffered model for calculating damages is based on

the place where each prescription was filled, not where each TPP paid any amount of money for the VCDs as required by the subclass definitions certified by the Court. This would necessarily result in improper recoveries for TPPs outside of the subclasses certified by the Court. Second, Plaintiffs have failed to present evidence setting forth a cognizable theory of damages under any state's applicable measure of damages. And third, Plaintiffs' request for punitive damages has no factual or legal merit.

A. Plaintiffs' Damages Model Cannot Establish Damages On A Classwide Basis.

The Court should grant Defendants summary judgment on the question of damages first and foremost because Dr. Conti's proposed damages model—the linchpin of Plaintiffs' request for monetary relief in this case—is not a viable method for calculating classwide damages. Although the Court defined each of the TPP subclasses by reference to specific states in which subclass members "paid any amount of money" for at-issue VCDs, Dr. Conti's damages calculation focuses solely on the "point of sale" where prescriptions were filled. As the undisputed record discloses, TPPs do ***not*** pay for the VCDs at these "points of sale." Rather, an intermediary like a PBM covers the transaction at the point of sale, and TPPs pay PBMs in a separate transaction with no necessary geographic connection to the point of sale. (SUMF ¶¶ 107, 109-11.)

Dr. Conti's approach of calculating damages based on the "point of sale" and not the TPPs' "point of payment" has two fatal implications for Plaintiffs' ability to prove damages at trial. First, Dr. Conti's damages model would award damages for TPPs ***outside*** of the subclass definitions and may also fail to award damages for TPPs ***within*** the subclass definitions, because her model does not identify the point of payment necessary to determine a TPP's inclusion or exclusion from a given subclass. Consider, for example, a TPP that paid a PBM in Delaware for VCD prescriptions filled in New York. That TPP would not be a member of any of the TPP Trial subclasses because it "paid any amount of money" for VCDs in Delaware, and Delaware is not listed in the class definition for any of the four subclasses set for trial.[11] Yet, Dr. Conti's model would award damages for those VCD prescriptions because they were filled in New York, which she erroneously treats as a TPP Class state. Conversely, her model would not award damages for a TPP that paid a PBM in New York for VCD prescriptions filled in Delaware, because the "point of sale" is outside of the four TPP Trial subclasses.

Dr. Conti does not even attempt to confront this irreconcilable conflict between her damages model and the subclass definitions. Plaintiffs' failure to offer a viable model to prove damages for the TPP Trial claims and subclasses further

[11] The states that are not included in any of the trial subclasses are Delaware, Indiana, Kansas, Kentucky, Maine, Maryland, Michigan, New Mexico and West Virginia. (*See* ECF 2343.)

entitles Defendants to summary judgment. *See In re Gen. Motors LLC Ignition Switch Litig.*, 407 F. Supp. 3d 212, 239 (S.D.N.Y. 2019) (flawed damages model required summary judgment).

Second, Dr. Conti's model makes it impossible to apply governing law under the standard set by this Court—i.e., that each TPP's claims are governed by "the law of each plaintiff['s] home state." (ECF 818 at 10.) For example, a TPP that paid a PBM for VCD prescriptions filled in Florida (where privity is not required) would be in express warranty subclass group b, even if its "home state" and the law governing its claim is Kentucky (where privity is required), meaning that privity would be required as to that TPP despite its inclusion in express warranty subclass group b. Yet, Dr. Conti has not even attempted to determine the TPPs' home states, making it impossible to ascertain for purposes of the damages calculation the law governing each TPP's claims.

In short, because Dr. Conti's model is mismatched both to the subclasses certified for trial and to the Court's choice-of-law ruling, it cannot support Plaintiffs' bid to prove damages. For this reason alone, Plaintiffs have no way to prove damages and Defendants are entitled to summary judgment.

B. Plaintiffs Cannot Prove Any Fraud- Or Warranty-Based Damages.

Even assuming that Plaintiffs had a damages model that matched the Court's subclasses, the record would not enable Plaintiffs to establish damages under any

recognized measure of damages. Nineteen of the 23 jurisdictions identified in the Court's subclasses follow the benefit-of-the-bargain standard in at least some cases of fraud—many of them exclusively so (*see* ECF 2261-3 at H-3, H-13, H-18 to H-19, H-22, H-29, H-31, H-33, H-40 to H-54)[12]—as does every state with respect to its breach of warranty laws.[13] Under the benefit-of-the-bargain standard, a plaintiff is entitled to damages representing "the difference between the price paid and the value of the property had the representations been true." *Finderne Mgmt. Co. v. Barrett*, 955 A.2d 940, 957 (N.J. Super. Ct. App. Div. 2008) (citation omitted). The benefit-of-the-bargain measure of damages does not yield measurable damages in pharmaceutical drug cases where, as here, plaintiffs do not allege any loss of efficacy or physical injury, because the "value" of an effective medication does not vary when additional risk information is disclosed. *See Heindel v. Pfizer Inc.*, 381 F.

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[12] *See also, e.g., BDO Seidman, LLP v. Mindis Acquisition Corp.*, 578 S.E.2d 400, 401 (Ga. 2003) (Georgia law uses "out-of-pocket standard for negligent misrepresentation and the benefit-of-the-bargain standard for fraudulent misrepresentation"); *Lightning Litho, Inc. v. Danka Indus., Inc.*, 776 N.E.2d 1238, 1243 (Ind. Ct. App. 2002) (similar); *Finderne Mgmt. Co. v. Barrett*, 955 A.2d 940, 957 (N.J. Super. Ct. App. Div. 2008) ("New Jersey recognizes benefit-of-the-bargain damages in fraud cases.").

[13] *See, e.g., Duyck v. Nw. Chem. Corp.*, 764 P.2d 943, 946 (Or. Ct. App. 1988) ("The measure of damages for breach of warranty is the difference at the time and place of acceptance between the value of the goods accepted and the value they would have had if they had been as warranted, unless special circumstances show proximate damages of a different amount.") (citation omitted); *Knox v. Ludwick*, No. 00CA2569, 2001 WL 1287156 (Ohio Ct. App. Sept. 25, 2001) (same).

Supp. 2d 364, 380 (D.N.J. 2004) ("[T]he decision to take a particular drug is a medical one, not one based on a[] comparative analysis of risk versus price.").

MSP also cannot prove that any TPP actually suffered an out-of-pocket loss, the measure of damages for common-law fraud in 12 of the 23 states at issue. (*See* ECF 2261-3 at H-3, H-13, H-18 to H-19, H-22, H-29, H-31, H-33, H-40 to H-54.) "Out-of-pocket damages represent the difference between the price paid and the actual value received." *Finderne Mgmt. Co.*, 955 A.2d at 957. Thus, the proper measure of damages in such states is not the difference in value received versus what a TPP expected to receive—like benefit-of-the-bargain damages—but the amount required to "restore the [TPPs] to the position [they] held prior to the" alleged fraud. *Murray v. Hadid*, 385 S.E.2d 898, 904 (Va. 1989).

Here, Plaintiffs could not have suffered any out-of-pocket loss because it is indisputable that, "[i]n their role as insurers, TPPs experience neither health benefits nor health risks." (SUMF ¶ 127.) Instead, TPPs have a contractual obligation with a beneficiary to fulfill a financial responsibility to pay for certain prescription medications and healthcare. Accordingly, whether there is an alleged "impurity" in a drug does not affect a TPP unless that impurity causes it to endure additional costs. *See Bryan v. Kissoon*, 767 N.W.2d 491, 496 (Minn. Ct. App. 2009) ("In jurisdictions like Minnesota that follow the 'out-of-pocket' rule, if the property is worth what a party paid for it, then that party has suffered no damages.").

Nor is there evidence that any TPP actually suffered an ascertainable loss or actual damages "that is quantifiable or measurable," as required by several states' consumer protection laws. *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 530 (D.N.J. 2011) (citations omitted). As previously discussed, the TPPs in this case would not only have had to pay for an alternative medication had the VCDs not been on the market, but they would have paid more money for that alternative medication. (*See* SUMF ¶ 130.)

For all of these reasons, Plaintiffs could not prove any entitlement to damages, even if they could prove the *prima facie* elements of their claims. This, too, entitles Defendants to summary judgment.

C. Plaintiffs Are Not Entitled To Punitive Or Exemplary Damages.

Finally, Defendants are entitled to summary judgment on Plaintiffs' request for punitive or exemplary damages.

As an initial matter, it is not possible to determine which state's punitive damages law(s) apply to each class member's claims for the reasons discussed above: the subclass is defined based on where payments were made by TPPs, whereas punitive damages should be governed by the law where the TPPs are based—i.e., the state with the most significant relationship to each TPP's claims. *See Gorji v. C.R. Bard, Inc.*, No. 4:21CV3134, 2022 U.S. Dist. LEXIS 34765, at *1 (D. Neb. Feb. 28, 2022) (applying "most significant relationship" test and applying law

of the plaintiff's home state; "Although Defendants here are, respectively, Utah and New Jersey corporations and have made business decisions in those states, this does not outweigh the contacts to Nebraska or Nebraska policy regarding punitive damages in this case."); *see also Seals v. Wright Med. Tech., Inc.*, No. 4:20-cv-01656-SRC, 2022 U.S. Dist. LEXIS 202223, at *11 (E.D. Mo. Nov. 7, 2022) (similar; "[W]hile Tennessee may have an interest in applying its punitive-damages laws to Tennessee corporations, Missouri has an interest in applying its own punitive-damages laws to 'inflict punishment and to serve as an example and deterrent to similar conduct' occurring in Missouri.") (citation omitted).[14] But even if the subclass states were the same as the states whose punitive damages laws apply, the claims would still fail.

First, two of the potentially relevant states—Nebraska and New Hampshire—proscribe punitive damages, warranting summary judgment with respect to Plaintiffs' requests for punitive damages under those states' laws. *See, e.g.*, *Dubas v. Clark Equip. Co.*, 532 F. Supp. 3d 819, 830 (D. Neb. 2021) (punitive damages prohibited under Nebraska's state constitution.); *Distinctive Printing & Packaging*

[14] "[A]s the decision of the United States Supreme Court [in *BMW of North America v. Gore*] makes clear, the treatment of punitive damages varies from state to state." *Sanders v. Johnson & Johnson, Inc.*, No. 03-2663 (GEB), 2006 U.S. Dist. LEXIS 35881, at *17-18 (D.N.J. May 31, 2008) (quoting *Mack v. Gen. Motors Acceptance Corp.*, 169 F.R.D. 671, 678 (M.D. Ala. 1996)) (citing *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996)).

Co. v. Cox, 443 N.W.2d 566, 574 (Neb. 1989) (similar) (citations omitted); N.H. Rev. Stat. Ann. § 507:16 ("No punitive damages shall be awarded in any action, unless otherwise provided by statute.").

Second, even assuming Plaintiffs could prove that Defendants breached any express or implied warranties, such a theory would not be a viable predicate for the imposition of punitive damages. Most states do not permit the recovery of punitive damages for breach of warranty theories. *See, e.g.*, *Parker v. Exterior Restorations, Inc.*, No. 21-0425-WS-B, 2022 WL 2532171, at *4 (S.D. Ala. July 7, 2022) (Alabama law "'is clear' that punitive damages are not recoverable for breach of warranty"); *Mahler v. KIA Motors Am.*, No. 6:17-cv-1770-MC, 2018 WL 1938430, at *2 (D. Or. Apr. 24, 2018) (same); *Bartlett Milling Co. v. Walnut Grove Auction & Realty Co.*, 665 S.E.2d 478, 487 (N.C. Ct. App. 2008) (punitive damages only available in tort under North Carolina law).

Although four of the warranty subclass states' laws apparently do permit recovery of punitive damages, they strictly limit such damages to exceptional cases involving egregious misconduct—i.e., "where the evidence demonstrates that there is willful or malicious conduct." *Hughes v. Segal Enters., Inc.*, 627 F. Supp. 1231, 1238 (W.D. Ark. 1986) (punitive damages ordinarily not recoverable for breach of warranty, but exception exists "where the evidence demonstrates that there is willful or malicious conduct" related to the breach); *Todd v. Kellum*, No. 1:15-cv-00177-

GHD-DAS, 2016 WL 4261919, at *3 (N.D. Miss. Aug. 10, 2016) (punitive damages not available absent "some element of aggression or some coloring of insult, malice or gross negligence, evincing ruthless disregard for the rights of others, so as to take the case out of the ordinary rule") (citations omitted); *Riley v. Gen. Motors, LLC*, 591 F. Supp. 3d 259, 277 (S.D. Ohio 2022) (punitive damages not permitted for breach of warranty unless conduct is so egregious it gives rise to "independent tort"); *Mohr v. DaimlerChrysler Corp.*, No. W2006-01382-COA-R3-CV, 2008 WL 4613584, at *15 (Tenn. Ct. App. Oct. 14, 2008) (egregious conduct required). Here, the record forecloses a finding of willful or malicious conduct on the part of any Defendant. As detailed above, this entire lawsuit is predicated on the presence of unknown and unanticipated impurities in VCDs that could not be detected by routine testing. (SUMF ¶¶ 57-76.) Even if the sale of such medications ran afoul of the relevant states' warranty laws, it would fall far short of engaging in knowing, intentional, malicious or egregious misconduct.

Third, Plaintiffs' fraud-based claims are also not a legitimate basis for recovering punitive damages or exemplary damages under state consumer-protection laws. Although the relevant state laws prescribe differing requirements and burdens of proof to support these kinds of damages, they generally impose exacting state-of-mind or culpability standards that Plaintiffs cannot establish. For example, the consumer-protection laws of Louisiana, New Hampshire, New York,

and North Dakota all require willfulness or knowing misconduct for the recovery of treble damages. *See Johnston v. Vincent*, 359 So. 3d 896, 919 (La. 2023) (treble damages can be sustained where the deceptive practice "was knowingly used after being put on notice by the attorney general"); *Lane v. Barletta*, 233 A.3d 335, 341 (N.H. 2019) (to be entitled to enhanced damages under the Consumer Protection Act requires a willful or knowing violation); *Samms v. Abrams*, 198 F. Supp. 3d 311, 317 (S.D.N.Y. 2016) (citing GBL 349(h) and stating that treble damages are appropriate "if the court finds the defendant willfully or knowingly violated this section"); *Mahanna v. Westland Oil Co.*, 107 N.W.2d 353, 359 (N.D. 1960) (similar).[15] And to the extent the relevant state consumer-protection laws ever permit the recovery of punitive damages, they generally require a showing of malice, oppression, or outright fraud. *See Holeman v. Neils*, 803 F. Supp. 237, 242-43 (D. Ariz. 1992) ("Punitive damages are allowed for violations of the Consumer Fraud Act where the wrongdoer's conduct is wanton or reckless, shows spite or ill will or where the conduct demonstrates a reckless indifference to the interests of others.");

[15] Many of the consumer-protection statutes only authorize treble damages of "ascertainable" losses. *See Kenai Chrysler Ctr., Inc. v. Denison*, 167 P.3d 1240, 1259-60 (Ala. 2007) (citation omitted) (violation coupled with ascertainable loss allows for recovery of treble damages); *Richards v. Ameriprise Fin., Inc.*, 152 A.3d 1027, 1035 (Pa. Super. Ct. 2016) (plaintiff must demonstrate an ascertainable loss as a result of the defendant's prohibited action to recover any damages under the UTPCPL). Because, as discussed *supra*, Plaintiffs cannot prove any such "ascertainable" losses, that is further grounds for precluding any classwide recovery of treble damages.

Roper v. Big Heart Pet Brands, Inc., 510 F. Supp. 3d 903, 926 (E.D. Cal. 2020) (punitive damages warranted "[w]here a plaintiff proves that the defendant has been guilty of fraud or malice"); *Gargano v. Heyman*, 525 A.2d 1343, 1347 (Conn. 1987) (stating that "the flavor of the basic requirement to justify an award of punitive damages is described in terms of wanton and malicious injury, evil motive and violence"); *Heckadon v. CFS Enters., Inc.*, 400 S.W.3d 372, 382 (Mo. Ct. App. 2013) (in determining reasonableness of punitive damages, the court considers, inter alia, whether "the harm was the result of intentional malice, trickery, or deceit, or mere accident") (citation omitted).

Moreover, in a number of the states in question, "[a] bare case of fraud or constructive fraud does not warrant the assessment of exemplary or punitive damages." *K. Ronald Bailey & Assocs. Co. v. Soltesz*, No. E-05-077, 2006 WL 1364019, at *3 (Ohio Ct. App. May 19, 2006); *see also, e.g.*, *Walker v. Sheldon*, 10 N.Y.2d 401, 405 (1961) (in New York, punitive damages "have been refused in the 'ordinary' fraud and deceit case"); *Davis v. N.C. State Highway Comm'n*, 156 S.E.2d 685, 686-88 (N.C. 1967) ("[I]t is 'the general rule that ordinarily exemplary, punitive, or vindictive damages are not recoverable in an action for fraud.'") (citation omitted); *Dixon v. Bohn*, 890 So. 2d 613, 615 n.2 (La. Ct. App. 2004) ("Punitive damages are not an element recoverable in an action for fraud.") (citing La. C.C. art. 1958). In other words, mere intentionality does not suffice; rather, the conduct in

question must also "evinc[e] a high degree of moral turpitude that demonstrates such wanton dishonesty as to imply a criminal indifference to civil obligations." *Princes Point, LLC v. AKRF Eng'g, P.C.*, 944 N.Y.S.2d 493, 494 (App. Div. 2012).

The record evidence regarding Defendants' alleged conduct does not give rise to punitive damages under any of the applicable states' laws because Defendants did not even know of the potential for the formation of trace amounts of purported impurities during the API manufacturing process prior to 2018, as discussed in the defendant-specific summary judgment motions, incorporated herein by reference. (*See also* SUMF ¶¶ 68-69.) As such, they could not have acted with the specific intent to defraud the TPPs, much less done so maliciously and with moral turpitude. For this reason as well, the class members encompassed by the common-law fraud and consumer-fraud subclasses have no basis for recovering punitive damages in this case.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants summary judgment on all of Plaintiffs' claims.

Dated: December 22, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 22, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
Jessica Davidson